

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD,
INC., POLYPROPYLENE HERNIA
MESH PRODUCTS LIABILITY
LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
Johns v. CR Bard, et al.,
Case No. 2:18-cv-1509

EVIDENTIARY MOTIONS ORDER NO. 8

Plaintiff Steven Johns filed a Motion to Exclude the Opinions and Testimony of Defense Expert Maureen T.F. Reitman, Sc.D. (ECF No. 114). For the reasons set forth below, Plaintiff's motion is granted in part and denied in part.

I. Background¹

This case is the first bellwether trial, selected from thousands of cases in this multidistrict litigation ("MDL"), alleging "that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions." (No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)² This includes the Ventralight ST, the device implanted in Plaintiff. The Ventralight ST is a prescription medical device used for hernia repairs. (ECF No. 309 at PageID #16717.) It is a multicomponent device made of a mesh, which consists of polypropylene, polyglycolic acid fibers, and a bioresorbable coating called "Sepra Technology" ("ST"). The ST-coated side of the mesh is placed against organs, such as the bowels, while the uncoated

¹ The Court assumes that the parties and other interested readers are familiar with the history of this case. For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order. (ECF No. 309.)

² Unless otherwise noted, record citations are to the docket for this case, No. 18-cv-01509.

polypropylene side is placed against the fascia because the uncoated side maximizes tissue attachment and thus supports the hernia repair. (*Id.*)

Plaintiff claims that he suffered omental adhesions from the implantation of Defendants' allegedly defective Ventralight ST device during a laparoscopic hernia repair in 2015. (*Id.* at PageID #16722.) He contends that Defendants knew that polypropylene is unsuitable for permanent implantation in the human body. (*Id.* at PageID #16717.) The crux of Plaintiff's claims is that the ST coating on Ventralight ST devices resorbs too quickly, exposing bare polypropylene to internal organs and tissues. This leads to oxidation of the polypropylene, which degrades and then causes complications like adhesions. (*Id.* at PageID #16717–18.) The following claims remain for trial: design defect, under negligence and strict liability theories; failure to warn, under negligence and strict liability theories; breach of express warranty; breach of implied warranty; breach of implied warranty of merchantability; negligent misrepresentation; and punitive damages. (*Id.* at PageID #16727–65.) Various evidentiary motions are now ripe for adjudication.

This evidentiary motion focuses on the expert report and deposition testimony of Dr. Reitman. Her expert report contains six main parts, as well as appendices. To begin, Dr. Reitman reviews and analyzes documents that inform her opinions. This discussion includes an overview of the regulatory process for and animal testing conducted on the Ventralight ST. (ECF No. 114-1 at PageID #7879, 7903, 7916.)

Then, Dr. Reitman's report catalogues her testing, which spans a variety of visual, microscopic, chemical, and thermal analyses. She analyzes Ventralight ST devices that have never been implanted ("exemplars") and those that have been removed from patients ("explants"). (*Id.* at PageID #7930.) Specifically, and relevant to Plaintiff's motion, Dr. Reitman reaches two main conclusions. Based on her exemplar testing, she determines that polypropylene is stable and highly

resistant to oxidation. (*Id.* at PageID #7930.) Based on her explant analysis, she concludes that the residue or “crust layer” on the explants was not evidence of oxidative degradation, as Plaintiff argues, but a “biologically based surface deposit.” (*Id.* at PageID #7948, 7971.) For greater context, Dr. Reitman’s testing is briefly described below.

First, Dr. Reitman explains her twenty-three-step cleaning process for the explants to remove “tissue and biological matter.” (*Id.* at PageID #7931–33.) Cleaning the explants revealed “uncracked” surfaces of the polypropylene fiber and “pristine, smooth surfaces,” though some of the “deposit” “remains as a cracked crust on the surface.” (*Id.* at PageID #7937.) Dr. Reitman conducted various tests on the cleaning solutions and the removed crust, concluding that there was no evidence of oxidative degradation. (*Id.* at PageID #7942.) She also examined the explants visually and with gravimetry, Fourier transform infrared spectroscopy (“FTIR”), optical microcopy, scanning electron microscopy (“SEM”), and Energy-Dispersive X-ray spectroscopy at determined points of the cleaning process. (*Id.* at PageID #7932 & nn.172–74.) Additionally, Dr. Reitman cleaned exemplars that had been intentionally oxidized and determined that the polypropylene was resistant to damage and that the crust chemistry and morphology could not be duplicated via oxidation. (*Id.* at PageID #7932.)

Next, the report details the visual and microscopic conditions of the samples, focusing on the crust present on the explants. (*Id.* at PageID #7948.) For example, Dr. Reitman concludes that the thickness of the crust does not “correlate with implant duration in the body . . . as would be expected for oxidative degradation.” (*Id.*) She also examined cross-sections of the samples and compared them. (*Id.* at PageID #7951.) Dr. Reitman observed that the cracks present in the intentionally oxidized exemplars were “markedly different” than the cracks present in the explants. (*Id.*) The explant cracks uniformly halted with blunt ends, suggesting that there were two materials

present—an outer crust and an underlying material. (*Id.*) On the other hand, the oxidized exemplars showed irregular, sharp cracks, suggesting only one material was present. (*Id.*)

Dr. Reitman moves on to a spectroscopic evaluation, which analyzes the surface of a material. (*Id.* at PageID #7955.) She determined that the surface composition of the explants was inconsistent with oxidation because there was no instance where the explants shared any characteristics that were similar to the intentionally oxidized exemplars. (*Id.* at PageID #7956.) To reach this conclusion, Dr. Reitman relied on FTIR analysis. (*Id.*)

Dr. Reiman also performed thermal tests on the exemplars, and she used differential scanning calorimetry (“DSC”) and thermogravimetric analysis (“TGA”) to evaluate the effects upon the polypropylene. (*Id.* at PageID #7957.) She determined that heating “well-above the melting and process temperatures” of the polypropylene in oxygen could bring about oxidation and left no residue behind. (*Id.*) However, Dr. Reitman found no evidence of degradation in the explants via DSC. When the same intense heating in oxygen was performed on the explants, a “shriveled film-like residue” remained, which was more common *before* the cleaning process, suggesting the residue was not made of the same material as polypropylene. (*Id.* at PageID #7957–58.)

The report moves on to examine the resistance of exemplars to chemical and forced oxidative degradation. (*Id.* at PageID #7959.) The exemplars were exposed to oxidation for more than sixteen hours at 160 degrees Celsius in pure oxygen without any evidence of degradation, which was tested by TGA and oxidation induction time (“OIT”). (*Id.*) Dr. Reiman also exposed exemplars to intense chemical oxidizers, finding no impact on the surface of the exemplars with FITR testing. (*Id.* at PageID #7960.) Only ultraviolet light forced the oxidation and degradation of the exemplars, which was analyzed with FITR, SEM, DSC, EDS, and OIT. (*Id.* at PageID

#7962–69.) Dr. Reiman found that the oxidized exemplars cracked further under weighted loads and post-oxidation cleaning, although the explants did not. (*Id.* at PageID #7963–64.) When Dr. Reiman compared these confirmed oxidized exemplars to the explants with other testing methods, she found dissimilarities. (*Id.* at 7964–69.)

Then Dr. Reiman’s report rebuts Plaintiff’s evidence regarding oxidation. (*Id.* at PageID #7970.) She also rebuts Plaintiff’s expert reports with particularity. (*E.g., id.* at #7981.) Within this portion of the report, she relies on an experiment by Exponent that involved soaking exemplars “in human serum for seven days and allowing it to dry to a coating,” which replicated the crust and revealed a “pristine fiber” when removed, as in her analysis. (ECF No. 114-4 at PageID #7973.)

Finally, Dr. Reitman offers her opinions. She opines generally that “to a reasonable degree of scientific and engineering certainty that polypropylene . . . is a reasonably selected biomaterial exhibiting appropriate biocompatibility,” that the Ventralight ST performs as intended, that the Ventralight ST is reasonable for use in surgery, and that no “action or inaction” by Defendants caused Plaintiff’s injuries. (ECF No. 114-5 at PageID #8021.) She also offers opinions that the Ventralight ST was not defectively manufactured, polypropylene is not oxidized in the body, polypropylene mesh does not oxidatively degrade in the body, and shrinkage or contracture in explants are normal and not indicative of oxidation. (*Id.* at PageID #8022.)

II. Legal Standards

“Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*.” *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions “has developed pursuant to the district court’s inherent authority to manage the course of

trials.” *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). “The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial.” *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because “a court is almost always better situated during the actual trial to assess the value and utility of evidence.” *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); accord *Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—“evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context.” *Ind. Ins. Co.*, 326 F. Supp. 2d at 846. The denial, in whole or in part, of a motion in limine does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins. Co.*, 326 F. Supp. 2d at 846.

Evidentiary rulings are made subject to the district court’s sound discretion, *Frye v. CSX Trans., Inc.*, 933 F.3d 591, 598 (6th Cir. 2019), including the admissibility of expert testimony, *United States v. Dunnican*, 961 F.3d 859, 875 (6th Cir. 2020). The Supreme Court has described a district court’s obligation to determine the admissibility of expert testimony as one of “gatekeeping,” ensuring that “any and all scientific testimony evidence admitted is not only relevant, but reliable.” *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 588, 597 (1993); *Kumho Tire Co. Ltd. v. Carmichael*, 526 U.S. 143, 141 (1999) (holding that the district court serves a gatekeeping function for non-scientific expert testimony). This role, however, is not intended to supplant the adversary system or the role of the jury. *In re Scrap Metal Antitrust Litig.*, 527 F.3d

517, 531–32 (6th Cir. 2008). Arguments regarding the weight to be given to any testimony or opinions of an expert witness are properly left to the jury. *Id.* “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert*, 509 U.S. at 596.

The burden is on the party proffering the expert testimony to demonstrate by a preponderance of proof that the opinions of their experts are admissible. *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001). Any doubts regarding the admissibility of an expert’s testimony should be resolved in favor of admissibility. Fed. R. Evid. 702 advisory committee’s note to 2000 amendment (“A review of the case law after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule.”); *Jahn v. Equine Servs., PSC*, 233 F.3d 382, 388 (6th Cir. 2000) (“The Court [in *Daubert*] explained that Rule 702 displays a liberal thrust with the general approach.”).

III. Analysis

Plaintiff argues that Dr. Reitman’s expert report and testimony are inadmissible. Expert testimony is admissible if:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. In this circuit, “[t]he Rule 702 analysis proceeds in three stages.” *United States v. Rios*, 830 F.3d 403, 413 (6th Cir. 2016). “First, the witness must be qualified by ‘knowledge, skill, experience, training, or education.’ Second, the testimony must be relevant, meaning that it

‘will assist the trier of fact to understand the evidence or to determine a fact in issue.’ Third, the testimony must be reliable.” *Id.* (citations omitted).

Along these lines, Plaintiff contends that Dr. Reitman is unqualified to offer her opinions, her opinions are irrelevant, and her methods used to reach her conclusions are unreliable. (ECF No. 114 at PageID #7845, 7850.) Dr. Reitman is unqualified to offer causation opinions that go beyond her area of expertise and opinions regarding the reasonableness of Defendants’ conduct, but the remainder of her opinions are admissible because she is qualified to offer them, they are relevant, and her methods are reliable.

A. Qualifications

An expert witness must be qualified by “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. “The issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question.” *Madej v. Maiden*, 951 F.3d 364, 370 (6th Cir. 2020) (quoting *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994)). “[T]he only thing a court should be concerned with in determining the qualifications of an expert is whether the expert’s knowledge of the subject matter is such that his opinion will likely assist the trier of fact in arriving at the truth. The weight of the expert’s testimony must be for the trier of fact.” *Mannino v. Int’l Mfg. Co.*, 650 F.2d 846, 851 (6th Cir. 1981). A party’s expert need only meet the “‘minimal qualifications’ requirement—not one who could teach a graduate seminar on the subject.” *Burgett v. Troy-Bilt LLC*, 579 F. App’x 372, 377 (6th Cir. 2014) (citing *Mannino*, 650 F.2d at 846); *see also Dilts v. United Grp. Servs., LLC*, 500 F. App’x 440, 446 (6th Cir. 2012) (“An expert’s lack of experience in a particular subject matter does not render him unqualified so long as his general knowledge in the field can assist the trier of fact.”). Plaintiff argues Dr. Reitman is not qualified

to offer causation, biocompatibility, regulatory, and legal opinions. (ECF No. 114 at PageID #7845.)

First, causation and biocompatibility. Dr. Reitman is qualified to opine on whether oxidative degradation of polypropylene fibers actually occurs in the human body based on her analysis of the explants and whether oxidative degradation could possibly occur based on her testing of the exemplars. Dr. Reitman is a materials scientist and a Principal Engineer and the Group Vice President responsible for Polymer Science, Materials Chemistry and Biomedical Engineering for Exponent, Inc. (ECF No. 29-5.) Dr. Reitman earned a Bachelor of Science in Materials Science and Engineering and a Doctor of Science in Materials Science and Engineering, with a thesis in the field of polymers, both from the Massachusetts Institute of Technology. (*Id.*) She has ample experience in studying medical plastics and devices, including biocompatibility from the perspective of material selection and design. (ECF No. 136-2 at PageID #8731, p. 9; 8736, p. 140; 8740, p. 192.) As Dr. Reitman explained in her deposition, “I work with questions of biocompatibility and material selection all the time. But my work is more directed at the material and the consideration of the biocompatibility measured by cell response, rather than the direct evaluations of the cell responses themselves.” (*Id.* at PageID #8736, p. 140.) Thus, Dr. Reitman is qualified to opine that oxidative degradation of the polypropylene could not have caused Plaintiff’s injuries because the polypropylene did not and cannot oxidatively degrade in the body, as well as that polypropylene is a suitable material from a biocompatibility perspective.

However, Dr. Reitman is not qualified to give a broad causation opinion such as “there is no evidence that . . . *any* action or inaction on the part of Bard related to these products[] caused the alleged injuries to Plaintiffs.” (ECF No. 114-5 at PageID #8021 (emphasis added).) She can speak to the specific issue of whether the design or manufacture of the Ventralight ST caused

Plaintiff's injuries by oxidatively degrading, which may suggest the answer to the ultimate question of causation—did Defendants cause Plaintiff's injuries. *Berry*, 25 F.3d at 1353 (“When the rules speak of an expert’s testimony embracing the ultimate issue, the reference must be to stating opinions that suggest the answer to the ultimate issue or that give the jury all the information from which it can draw inferences as to the ultimate issue.”). But Dr. Reitman’s expertise ends there, and so she cannot provide such sweeping opinions.

Plaintiff counters that Dr. Reitman has no biological, medical, or biomedical engineering education, and therefore she cannot opine how polypropylene reacts within the body, including the inertness of, stability of, and impact of implantation on the polypropylene. (*See id.* at PageID #7845–47.) Dr. Reitman does not purport to opine on the body’s biological response, however. Her opinions are limited to the suitability and characteristics of the polypropylene, which she is eminently qualified to opine on as a materials scientist and given her experience in material selection for medical devices. This includes whether and when polypropylene can oxidize, the effect of implantation in the human body on the material, and whether the material is inert and stable within the body. Importantly, Dr. Reitman provides caveats, noting that she only acknowledges that cells respond to certain materials and that she does not attempt to determine the nature or meaning of the cell response itself. She does not attempt to give an opinion on the reaction of the body to the polypropylene. *Cf. Salinero v. Johnson & Johnson*, No. 1:18-cv-23643-UU, 2019 WL 7753453, at *15 (S.D. Fla. Sept. 5, 2019) (concluding that a chemical and biomolecular engineer was “not qualified to opinion about clinical manifestations of the body’s response to implants,” “such as pain and scarring”).

Plaintiff appears to seek a per se rule that any opinion that implicates biology or medicine requires a degree in biology or medicine (*id.* at PageID #7845 (“Dr. Reitman is not a medical

doctor or a biomedical engineer; she has never explanted or implanted mesh”)), but Rule 702 is not so restrictive—education, training, or experience suffices. *See also Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 2939521, at *20–21 (S.D. W. Va. May 19, 2016) (suggesting experience with such devices would confer expertise). “[I]nsistence on a certain kind of degree or background is ‘at odds with the “liberal thrust” of the Federal Rules and their “general approach of relaxing the traditional barriers to ‘opinion’ testimony.’” ‘The language of Rule 702 and the accompanying advisory committee notes make clear that various kinds of “knowledge, skill, experience, training, or education,” qualify an expert as such.’” *In re Heparin Prods. Liab. Litig.*, 803 F. Supp. 2d 712, 731 (N.D. Ohio 2011) (citations omitted). Plaintiff cannot ignore Dr. Reitman’s ample experience with medical devices.

Second, “regulatory” opinions. Plaintiff argues that Dr. Reitman is unqualified to give the opinion that polypropylene “ha[s] been repeatedly tested to confirm biocompatibility according to objective and scientific methods accepted by the FDA and other regulatory agencies.” (ECF No. 114 at PageID #7847; ECF No. 114-5 at PageID #8022.) Plaintiff classifies this as a “regulatory opinion.” (ECF No. 114 at PageID #7848.) Plaintiff misconstrues Dr. Reitman’s opinion, however. This is not a regulatory compliance opinion; the FDA itself explains that “[g]uidance documents . . . do not operate to bind FDA or the public.” Guidance Documents (Medical Devices and Radiation-Emitting Products), FDA, <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products> (last visited Feb. 22, 2021). Moreover, these guidance documents are written for the regulated industries, among others, indicating that industry participants stand to read, understand, and then implement the guidance. Given her experience with device manufacturing and design and implementation of scientific protocols, particularly product development, Dr.

Reitman is qualified to opine whether Defendants followed the protocols suggested by the FDA, though she may not opine whether Defendants are in compliance with the FDA. Thus, Dr. Reitman's conclusion that Defendants followed various types FDA guidance, including protocols for product development, performance specification, design validation, and more (ECF No. 114-2 at PageID #7907–08 & nn.56–75), is not an impermissible regulatory compliance opinion. *Cf. Tyree v. Bos. Sci. Corp.*, 54 F.Supp.3d 501, 550–51 (S.D. W. Va. 2014) (explaining that a medical doctor could not opinion on the adequacy of warnings and FDA compliance).

Finally, Plaintiff argues that Dr. Reitman is not qualified to offer legal opinions, including whether the devices at issue in this MDL are defective or state of the art and the Defendants' state of mind or the reasonableness of their conduct. (ECF No. 114 at PageID #7848–50.) Federal Rule of Evidence 704 provides that “[a]n opinion is not objectionable just because it embraces an ultimate issue.” Fed. R. Evid. 704(a); *United States v. Maya*, 966 F.3d 493 (6th Cir. 2020). “Nonetheless, a witness may not testify to a legal conclusion.” *Hyland v. HomeServices of Am., Inc.*, 771 F.3d 310, 322 (6th Cir. 2014). “[T]here is a ‘subtle,’ but ‘nonetheless important’ distinction between ‘opin[ing] on the ultimate question of liability (impermissible),’ and ‘stating opinions that suggest the answer to the ultimate issue or that give the jury all the information from which it can draw inferences as to the ultimate issue.’” *Babb v. Maryville Anesthesiologists P.C.*, 942 F.3d 308, 317–18 (6th Cir. 2019) (quoting *Berry*, 25 F.3d at 1353).

Dr. Reitman may not offer opinions as to whether the Ventralight ST is defective or whether Defendants acted reasonably, though she may offer a state-of-the-art opinion. As the Court has previously held in this case, an expert may not opine whether they consider a device defective. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Case Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6605612, at *6 (S.D. Ohio. Sept. 11, 2020). Dr.

Reitman may offer opinions related to the appropriateness of polypropylene as a material for an implantable device or the appropriateness of certain aspects of the design of the polypropylene mesh from her perspective as a materials scientist and experience in medical device development. Anything further, however, and her opinion moves beyond embracing an ultimate issue to opining on an ultimate issue. On the other hand, Dr. Reitman may explain whether the Ventralight ST was a state-of-the-art device based on her extensive involvement in device design and manufacturing and education and training as a materials scientist. *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 345 F.Supp.3d 897, 903 (S.D. Ohio 2015) (collecting cases). But Dr. Reitman may not then take her testimony one step further and offer an opinion whether Defendants' conduct was reasonable in relation to the selection of polypropylene. This is the inference the Defendants hope the jury will draw from her testimony. But only the jury can draw the inference. Although her testimony will undoubtedly embrace the ultimate issue of whether Defendants' conduct was reasonable, she may not characterize Defendants' conduct so.

For the reasons above, Dr. Reitman is qualified to offer her opinions and testimony with the exception of three opinions: (1) that no action of Defendants in relation to product development caused Plaintiff's injuries, (2) that the Ventralight ST is not defective, and (3) that Defendants' conduct was reasonable.

B. Relevance

Expert testimony must also be relevant, meaning it will "help the trier of fact to understand the evidence or to determine a fact in issue." *Bradley v. Ameristep, Inc.*, 800 F.3d 205, 209 (6th Cir. 2015) (quoting *United States v. Cunningham*, 679 F.3d 355, 379–80 (6th Cir. 2012)); Fed. R. Evid. 702(a). "Expert testimony which does not relate to any issue in the case is not relevant, and, ergo, non-helpful." *Daubert*, 509 U.S. at 591. "This requirement has been interpreted to mean

that scientific testimony must ‘fit’ the facts of the case, that is, there must be a connection between the scientific research or test result being offered and the disputed factual issues in the case in which the expert will testify.” *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000) (citing *Daubert*, 509 U.S. at 592). “Whether an opinion ‘relates to an issue in the case’ or helps a jury answer a ‘specific question’ depends on the claims before the court.” *Madej*, 951 F.3d at 370.

Dr. Reitman’s data and opinions are relevant to this case. Plaintiff’s theory of causation is that the polypropylene mesh degraded via oxidation, causing him injury. Dr. Reitman subjected exemplar devices to even more intense opportunities for oxidation than those in the human body, concluding that polypropylene does not oxidatively degrade in the body. (ECF No. 114-5 at PageID #8022.) Among other opinions, she also opined that the crust present on the explants was not evidence of oxidation, but biological material, based on her comparisons of the explants to the exemplars and other independent testing of the explants. (*Id.*) Whether oxidation is possible within the human body and whether the crust is evidence of oxidation is useful evidence to a jury determining whether oxidation of the polypropylene in the Ventralight ST caused Plaintiff’s injury.

Plaintiff unconvincingly argues that some of Dr. Reitman’s data and opinions are irrelevant to the extent that they fail to mimic the environment of the body, explaining that most of Dr. Reitman’s testing involved more aggressive or harsher environments than that of the human body. (ECF No. 114 at PageID #7846 & nn.3–5.) Specifically, Plaintiff contends that Dr. Reitman’s intentionally oxidized exemplars do not show the pertinent form of oxidation; the intentionally oxidized exemplars have oxidation through the entire polypropylene fiber while devices oxidized in the body show a layer-by-layer oxidation. (ECF No. 149 at PageID #9394–95.) But disagreement between the parties regarding the identity of the crust on the explants does not show that Dr. Reitman’s opinions are irrelevant—this simply highlights the disagreement between the

parties regarding what the crust of the polypropylene fibers is and what evidence of oxidation *in vivo* looks like on the polypropylene fibers.

C. Reliability

Expert testimony must also be reliable. Rule 702 provides the following general standards to assess reliability: whether the testimony is based upon “sufficient facts or data,” whether the testimony is the “product of reliable principles and methods,” and whether the expert “has applied the principles and methods reliably to the facts of the case.” Fed. R. Evid. 702(b)–(d). To evaluate reliability of principles and methods, courts consider ‘testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique’s operation, and general acceptance in the relevant scientific community,’ though “[t]hese factors ‘are not dispositive in every case’ and should be applied only ‘where they are reasonable measures of the reliability of expert testimony.’” *In re Scrap Metal*, 527 F.3d at 529 (quoting *Gross v. Comm’r*, 272 F.3d 333, 339 (6th Cir. 2001)); *Madej*, 951 F.3d at 374 (describing these factors as flexible). The objective of the reliability requirement is to “make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire*, 526 U.S. at 152. Plaintiff argues that Dr. Reitman’s methods are unreliable, pointing primarily to her cleaning procedure of the exemplars, failure to follow written protocols for some types of analyses, and incomplete record keeping, but Plaintiff’s protestations amount to disagreements with Dr. Reitman’s results and do not show that her methods are unreliable.

1. Cleaning procedure

Plaintiff raises a long list of arguments that go to the lack of reliability of Dr. Reitman’s cleaning procedure, but none are persuasive. First, Plaintiff argues that the cleaning procedure is

not a generally accepted scientific method. (ECF No. 114 at PageID #7851.) Dr. Reitman relied on a published article in the International Urogynecology Journal from 2017 for the cleaning procedure. (ECF No. 136 at PageID #8707.) This is a peer-reviewed article, which suggests the method is generally accepted. Plaintiff argues that the article was written after polypropylene mesh litigation began and that some of the authors may have biases (ECF No. 149 at PageID #9391–93 & n.9.) But a method need not be infallible or lack any weaknesses to be reliable. This is a weight of the evidence issue for the jury.

Plaintiff also takes issue with Dr. Reitman’s use of an orbital shaker and the particular bleach and Proteinase K concentrations in the cleaning, but this says nothing of whether the method is reliable. These steps of the cleaning process are well-documented in the literature that Dr. Reitman cites in her report. (ECF No. 114-2 at PageID #7932.) Moreover, there is nothing in the record that suggests Dr. Reitman deviated from the procedure or manipulated the protocols.³ See *Nilavar v. Mercy Health Sys.-W. Ohio*, 244 F. App’x 690 697 (6th Cir. 2007) (evidence of manipulation); *Sanchez v. Boston Sci. Corp.*, No. 2:12–cv–05762, 2014 WL 4851989, at *7 (S.D. W. Va. Sept. 29, 2014) (deviation from protocol by failing to replicate a step).⁴ The crux of this argument is that Plaintiff disagrees with Dr. Reitman’s assessment that the crust on the explants is

³ Plaintiff suggests that Dr. Reitman increased the concentration of bleach in the cleaning process (ECF No. 114 at PageID #7852), but Dr. Reitman testified that she used a “standard bleach treatment” (ECF No. 114-6 at PageID #8056, p. 298) and that the only variable in the cleaning process was the amount of time of the bleach exposure (ECF No. 114-2 at PageID #7833, fig. 10).

⁴ Plaintiff cites *Sanchez* and other caselaw for the proposition that a reliable method in this case must simulate the conditions of the human body. (ECF No. 114 at PageID #7855.) However, one case addresses whether a method replicates *in vivo* conditions under relevance, which this opinion has already done. See *Botnick v. Zimmer, Inc.*, 484 F. Supp. 2d 715, 721 (N.D. Ohio 2007). And in *Sanchez*, the problem with the expert’s methodology was not that the expert failed to replicate *in vivo* conditions, but that the expert deviated from the peer-reviewed methodology. 2014 WL 4851989, at *7. Critically, whether expert testimony is relevant or reliable is a case-by-case determination, and there is no per se rule that protocols for testing mesh materials must mimic *in vivo* conditions. Dr. Reitman performed testing to determine whether it was possible—under even harsher conditions than those in the human body—for the polypropylene to oxidize. Under these circumstances, her opinion that the polypropylene could not oxidize is relevant and at the least, her methods for causing oxidation in the exemplars do not fail to be reliable simply because they did not only mimic *in vivo* conditions.

a biological coating, not oxidation, and Plaintiff asserts that Dr. Reitman's cleaning process removes the evidence of oxidation. (*Id.* at PageID #7853.) But in assessing the reliability of a method, the "focus, of course, must be solely on principles and methodology, not on the conclusions they generate." *Daubert*, 509 U.S. at 595.

Relatedly, Plaintiff asserts that Dr. Reitman's cleaning procedure requires subjective determinations, which renders the method unreliable. (ECF No. 114 at PageID #7851.) Plaintiff takes particular issue with Dr. Reitman's answers that the extent of cleaning depends on the amount of biological tissues and crust stuck to the explants. That Dr. Reitman made subjective determinations regarding the duration of each step of the cleaning process based on what she perceived to be biological matter left on the exemplars is worthy of cross examination at trial. But Plaintiff provides no authority that *any* subjective determination renders a method unreliable. For example, in other mesh litigation, courts have expressly rejected arguments that visual observations, which are inherently subjective, are unreliable methods. *In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-CV-4301, 2014 WL 186872, at *23 (S.D.W. Va. Jan. 15, 2014).

Plaintiff also argues that Dr. Reitman does not clearly indicate what degree of cleaning each sample underwent, how long it spent during each step of the cleaning process or provide other information indicating the exact history of the cleaning process each explant underwent. (ECF No. 114 at PageID #7851–52.) Although this appears to be a weakness of Dr. Reitman's method, it does not render the method unreliable because Dr. Reitman took other steps to confirm that she was not removing oxidized polypropylene during the cleaning. She validated the cleaning process with various methods, such as by comparing the explants with intentionally oxidized exemplars to look for evidence of oxidation and by analyzing the cleaning solutions for evidence of oxidized

polypropylene. (ECF No. 136 at PageID #8709.) Plaintiff argues that she did not measure the thickness or “amount” of material removed from the explants (ECF No. 114 at PageID #7852), but whether Dr. Reitman’s controls and validation are sufficient is cross-examination fodder, not an indication that her method was unreliable. *See In re Ethicon*, 2014 WL 186872, at *23 (explaining that the failure of an expert to test the removed material in the same cleaning process did “not render his methods unreliable” because he visually examined the mesh, concluding that there was no damage to the mesh, though the “methods appear to provide strong ammunition for cross-examination”).

Additionally, Plaintiff asserts that Dr. Reitman omitted portions of the cleaning procedure and that “she could not adequately recall or expand on [the cleaning procedures] during her deposition.” (ECF No. 114 at PageID #7851–52.) What omissions Plaintiff refers to, besides noting the degree and length of cleaning at certain steps, is unclear. Plaintiff also mischaracterizes Dr. Reitman’s testimony. In one instance, Plaintiff points to a portion of Dr. Reitman’s testimony where she discusses her understanding of the scientific method as not “requir[ing] peer review.” (ECF No. 114-6 at PageID #8037, pp. 144–45.) In another, later deposition testimony demonstrates that Dr. Reitman was able to recall additional details, such as how exemplars were received and tested. (*Id.* at PageID #8041–42, pp. 179–84.) These are not omissions or an inability to recall.

2. *Failure to provide written protocols for other methods of analysis*

Next, Plaintiff asserts that “Dr. Reitman failed to provide written testing protocols” for her analysis with SEM, FTIS, DSC, and TGA. (ECF No. 7854.) Plaintiff ignores that Dr. Reitman’s report indicated that she followed ASTM International standards for each analysis. For example, Dr. Reitman indicates the standard used, the instrument model used, and the manner in which

samples were run, such as temperature and length of time, for the DSC and TGA testing. (ECF No. 114-8 at PageID #8095 nn.2–3.) Plaintiff points to Dr. Reitman’s testimony that the ASTM standards “provides a framework for performing FTIR analysis. It is not overly perspective. And so we used the portion that is relevant for the setup and analysis.” (ECF No. 114-6 at PageID #8047 at pp. 222–23.) But Dr. Reitman goes on to describe the “standard process” as described in the ASTM standard. (*Id.*) The maintenance of standards is an indicator of reliability, *In re Scrap Metal* 527 F.3d at 529, but there is no indication that a standard must involve a rigid, itemized protocol that is separately produced from a well-known standard or framework. Dr. Reitman identified the generally accepted ASTM International standards that she used in her analyses and indicated the relevant variables and settings, as well as other specifics of her methodology. (*E.g.*, ECF No. 114-7 at PageID #8068 n.3 (noting the ASTM International standard, the settings of the machine, and how the data was represented from 128 scans).) Plaintiff does not explain why ASTM International standards are insufficient to demonstrate reliability, such as what information is missing and how that information is necessary to ensure reliability.

3. *Unreliable record keeping, handling of samples, and other arguments*

Plaintiff raises other miscellaneous arguments. First, he argues that Dr. Reitman did not include information about the tools she used to cut the samples, whether sterilization was used, how the samples were stored, and if samples were used across different tests. (ECF No. 114 at PageID #7854.) But as Defendants point out, the ASTM International standards for SEM, FTIR, DSC, and TGA analyses do not address these issues, and Plaintiff fails to explain how these issues render the spectrometry, heat, and chemical tests unreliable. Dr. Reitman relied upon generally accepted standards, and without more explanation from Plaintiff why these standards are unreliable *despite* being generally accepted, this lack of information does not render the standards unreliable.

Next, Plaintiff repackages his argument that Dr. Reitman's other testing relies on subjective determinations, such as in the FTIR analysis. (ECF No. 114 at PageID #7855.) Dr. Reitman testified that the FITR analysis required a determination whether an "acceptable signal" was received during the analysis. (ECF No. 114-6 at PageID #8053, p. 278.) But how this determination renders the entire FITR method unreliable is unclear. As stated above, subjective determinations do not necessarily remove all reliability from an expert's method.

Finally, Plaintiff asserts that Dr. Reitman does not provide sufficient information about the samples provided to Dr. Reitman during her past litigation experience, such as who provided the samples, or sufficient information about the samples tested for this particular report. (ECF No. 114 at PageID #7855–56.) In the report, Dr. Reitman documents the exemplars as she receives them with photographs. (ECF No. 114-7 at PageID #8085–92.) She also testified that "the general procedure is to receive a product as it would be delivered into the market place. So sterile conditions, unopened package, receive the product and do a basic assessment." (ECF No. 114-6 at PageID #8042, p. 182.) Without meaningful explanation from Plaintiffs why the tools, type of sterilization, and storage of polypropylene matters, the Court will not infer fatal unreliability in Dr. Reitman's approach. As for the explants in this litigation, Case Management Order No. 13 provides a stipulated protocol for handling mesh explants. (No. 18-md-2846, ECF No. 76.)

Finally, Plaintiff argues that the explants in past litigations lack information about the methodology applied, *i.e.* whether the same cleaning procedure was applied. (ECF No. 149 at PageID #9391.) This is unfounded. Dr. Reitman's report lays out the procedure for cleaning, and there is no suggestion in the report that the same procedure did not apply to every explant in her analysis. (ECF No. 114-2 at PageID #7931.) Indeed, Plaintiff points to the Avaulta products as past-litigation explants, but Dr. Reitman expressly states that her testing included the Avaulta

products before she sets forth the cleaning procedure. (*Id.* at PageID #7931 n.171.) Plaintiff attempts to conjure ambiguities in Dr. Reitman's report, which even if they existed must be resolved in favor of the admission of Dr. Reitman's testimony.

IV. Conclusion

Accordingly, Plaintiff's motion to exclude Dr. Reitman's opinions and testimony (ECF No. 114) is **GRANTED IN PART AND DENIED IN PART**. Plaintiff's motion is **GRANTED** as to Dr. Reitman's opinions that addresses whether "any act" of Defendants caused Plaintiff's injury, the reasonableness of Defendants' actions, and whether the Ventra light ST is defective. The motion is **DENIED** in all other respects.

IT IS SO ORDERED.

3/9/2021
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE